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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,627	04/29/2005	Peggy Wingard	006050.00067	2806

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1614	

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12/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,627	WINGARD ET AL.	
	Examiner	Art Unit	
	Darryl C. Sutton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *1-11 and 14-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/29/2004, 1/26/2005, 3/29/2005, 9/13/2005, 10/25/2005, 1/27/2006, 9/21/2006, 1/12/2007.

DETAILED ACTION

Applicant's election with traverse of the restriction and election of species in the reply filed on 11/16/2007 is acknowledged. The traversal is on the ground(s) that the Groups 1-XI do form a general single general inventive concept, and therefore, the examiner has applied improper standard for unity of invention. This is not found persuasive because the unity of invention standard as discussed in MPEP 1893.03(d) states:

> A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. **The expression special technical features is defined as meaning those technical features that define the contribution which the claimed invention, considering as a whole, makes over the prior art**. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.

(emphasis added). The examiner has considered the claims as a whole. The compounds of formula I, disclosed in the instant application are known in the art, along with methods for their use for initiation and maintenance of general anesthesia and sedation (see Stella, U.S. 6,204,257). Since compounds of formula I used to produce an anesthetic effect is disclosed as the "common special technical feature" of Groups I-XI on page 2 of applicant's remarks, lack of unity exists between all of the groups, I-XI because the special technical feature does not make a contribution, as a whole, over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election of Group IV, along with corresponding claims 12, 13 and new claim 36 in the reply filed on 11/16/2007 is acknowledged. Claims 1-11 and 14-35 are withdrawn from further consideration as being drawn to non-elected subject matter.

Drawings

The drawings are objected to because figure 2 in not legible. One of ordinary skill in the art would not be able discern the information that is germane to the claimed invention. A corrected drawing sheet in compliance with 37 CFR 1.121(d) is required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

IDS

There are problems with the applicant's IDS statements:

IDS filed 1/26/2005: Two foreign patent documents on page 1 have not been considered because no English translation was provided by the applicant. The NPL document on page 3 has not been considered because it does not have a date of publication included. The NPL on page 4 of the IDS has not been considered because a copy was not sent with the application.

IDS filed 3/29/2005: The NPL on page 2 has not been considered because no English translation as provided by the applicant.

IDS filed 10/25/2005: The foreign patents documents on page 1 (B001, B002, and B004) have not been considered because no English translation was provided by the applicant.

IDS filed 1/27/2006: The NPL listed on page 2 has not been considered because it is has already been considered on the IDS filed 10/25/2005.

IDS filed 1/12/2007: The foreign patent document, citation 1 is the same as citation 2. And, citations 2 and 3 referred to the same document.

The problems must be corrected in order for the examiner to consider these pieces of prior art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12, 13 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al. (U.S.) in view of Lowrie et al. (Pediatrics, 1998)

The claims are drawn to a method of producing a sedated state in a subject comprised of administering to a subject in need thereof a compound in at least one parenteral bolus injection of an amount of about 2 mg/kg to about 10 mg/kg to an amount of about 5 mg/kg to about 7.5 mg/kg.

Stella et al. teaches a method for the induction or maintenance of general anesthesia by administering compounds of formula I, propofol prodrugs, according to

procedures for induction or maintenance of general anesthesia and that the administration is preferably parenterally at the dosage in the range of 0.5 to 10 mg/kg (column 9, lines 1-32). Stella teaches that one skilled in the art of anesthesia will be able to ascertain, without undue experimentation, an appropriate treatment protocol for administering the compound (column 9, lines 13-18). Stella et al. also teaches that prodrugs of propofol, such as those of formula I, are cleaved *in vivo* to generate the parent drug, propofol (column 8, lines 25-40, page 9, lines 1-11).

Stella et al. does not explicitly teach a bolus injection of the claimed compound to produce a sedated state or the amounts of compound in the bolus injection.

Lowrie et al. teaches that the standard for patient sedation for the Pediatric Sedation Unit is to give propofol intravenously, first as a slow bolus of 1-2 mg/kg, and then continuous infusion (page 5, 1st column, 1st paragraph).

At the time of the invention, it would have been obvious to one skilled in the art to modify the method of Stella et al. and administer a bolus injection of 1-2 mg/kg of the compound of formula I to produce a sedated state, since the compound would generate propofol *in vivo* and propofol in those amounts has been used to produce a sedated state in children. Sedation is a form of anesthesia that ranges from conscious sedation to a deep sedated state. The compound would be reasonably expected to be used for adults and the physiological differences between adults and children would necessitate the need for different dosages. Therefore, it also would have been obvious to optimize the amounts of compound in the bolus injection to produce the desired level of sedation and to account for the compound being used to sedate adults.

All claims have been rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

DCS

Ardin H. Marschel 12/3/07

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER